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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/434,965	11/05/1999	ALAIN T. LUXEMBURG	ORT-1060	4589

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EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT PAPER NUMBER

1644

DATE MAILED: 09/22/2003

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/434,965

Applicant(s)

LUXEMBURG ET AL.

Examiner

F. Pierre VanderVegt

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/7/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

The Examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to F. Pierre VanderVegt, Ph.D. in Art Unit 1644.

This application is a continuation of U.S. Application Serial Number 08/909,549.

Claims 1-15 and 19-26 were previously canceled.

Claims 16-18 are currently pending and are the subject of examination in the present Office Action.

In view of Applicant's amendment filed February 7, 2003, no prior ground of rejection is maintained. The following represents a new ground of rejection that has been necessitated by Applicants amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment to claim 16 filed February 7, 2003 adds the recitation "wherein said Class I molecules are K^{bm3} or L molecules." Applicant contends that that amendment is supported at page 6, lines 24-25 of the specification. However, the relied-upon passage of the specification recites only L^d, K^b and K^{bm3} as the Class I molecules. Accordingly, the recitation of "L molecules" in the claim constitutes new matter, as the specification identifies only "L^d molecules." Dependent claims 17 and 18 are included in this ground of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burshtyn et al (Journal of Immunology (1993) 151:3070-3080; U on form PTO-892; of record).

It was previously stated: "Burshtyn et al teach a substrate for capturing peptide antigens comprising empty H-2D^b molecules bound to agarose beads. When said beads were incubated with human B₂Microglobulin, high affinity binding sites were created for an influenza peptide antigen, (see entire article, including the Abstract). Therefore, the referenced teachings anticipate the claimed invention."

Applicant's arguments filed February 7, 2003 have been fully considered but they are not persuasive. Applicant has amended claim 16 to recite "wherein said Class I molecules are K^{bm3} or L molecules" and contends that the claims are differentiated from the prior art because the Burshtyn reference does not specifically recite K^{bm3} or L Class I molecules. The Examiner respectfully disagrees.

The "New Matter" issue addressed *supra* notwithstanding, the amendment, while overcoming the particular issue of "anticipation" over the prior art, does not render the claims patentable over the prior art reference. The method taught by Burshtyn is taught as a method that can be applied by one of ordinary skill in the art to any Class I molecule of interest. Indeed, Burshtyn teaches that, "these uniform populations of bead-bound class I complexes will also prove useful in the further analysis of CTL target structure formation and recognition" at page 3080, column 1 in particular. Burshtyn recognizes that empty class I molecules are unstable, but addresses the problem well known in the art with the present method and teaches in the paragraph bridging pages 3079-3080 (in particular):

"[b]ecause class I complexes that lack peptide are known to be unstable, empty complexes might not survive affinity purification. In our case, the recovery of empty D^bβ_{2m} complexes preexisting in the cells was favored by isolating the proteins under

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conditions of low temperature and a high solubilization density. Furthermore, by not eluting the class I molecules from the affinity matrix we preserve empty complexes that are subsequently able to bind added peptide."

Furthermore, Burshtyn teaches at page 3070, column 2 in particular, that quantitative data regarding the class I L^d molecule had been previously obtained. It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to apply the teachings of Burshtyn to K^{bm3} or L Class I molecules. One would have been motivated, with a reasonable expectation of success, to apply the teachings of Burshtyn to additional class I molecules because the reference teaches that peptide binding information is available for class I molecules, such as L^d, other than the D^b exemplified and because Burshtyn teaches that class I molecules bound to the agarose beads are reusable, reducing the need for costly and time consuming additional purifications.

Conclusion

3. No claim is allowed.

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (703) 305-4441. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in

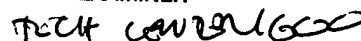
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Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
September 15, 2003



PHILLIP GAMBEL, PH.D.
PRIMARY EXAMINER



9/17/03